SECTION 7 - 510(K) SUMMARY OF SAFETY & EFFECTIVENESS

MODIFIED NAVIAID™ BGC DEVICE

AUG - 9 2011

510(k) Number K111760

Applicant's Name:

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Contact Person:

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Name of the device:

NaviAid™ BGC device

Trade or proprietary name, if applicable:

NaviAid™ BGC device

Common or usual name:

NaviAid™ Balloon Guided Colonoscopy (NaviAid™ BGC Device)

Establishment Registration No.:

3005261802

Classification Name:

Endoscope and accessories

Classification:

FDA has classified Endoscope and accessories devices as a Class II medical device, with product code ODC and 21 CFR classification code 876.1500. Review by the Gastroenterology/Urology Devices Panel.

Predicate Device:

The modified NaviAid™ BGC device is substantially equivalent to the cleared NaviAid™ BGC device (manufactured by Smart Medical Systems Ltd. and the subject of 510(k) document no. K102616) and to the cleared NaviAid™ ICVI device (manufactured by Smart Medical Systems Ltd. and the subject of 510(k) document no. K110291). A comparison table and detailed discussion are presented in Section 10 of this application.

Device Description:

The modified NaviAid™ BGC is an on-demand disposable that is inserted through the instrument channel of the endoscope in order to enable advancement and positioning of a standard endoscope in the small and large intestine.

The modified NaviAid™ BGC system comprises a disposable balloon system and an Air Supply Unit ("ASU") or a Single Balloon - Air Supply Unit ("SB ASU") for inflating and deflating the balloon system.

The role of the BGC disposable is to facilitate advancement of a standard endoscope into the small and large intestine. The NaviAid™ BGC disposable includes the BGC Balloon and the BGC inflation tube. The balloon is inflated by ambient air. The ASU or SB ASU operate and control the inflation and deflation of the balloon through a foot-pedal. The balloon is connected to a dedicated inflation tube that runs inside the instrument channel of the endoscope, and is connected at its proximal (user) end to the ASU or SB ASU.

The BGC balloon can be advanced ahead of the endoscope tip or pulled back through pushing/pulling action on the BGC inflation tube at its proximal side, outside the patient's body. When the BGC balloon is advanced and then inflated, it functions as a distal anchor, to which the endoscope tip is advanced, and the BGC inflation tube serves as a rail that leads the endoscope as it is pushed towards the anchoring BGC balloon.

The balloon and tube negligibly compromise the endoscope's flexibility, or its field of view. Additionally, the BGC disposable negligibly compromise the maneuverability of the endoscope's tip and does not limit the usage of any standard endoscopy tools. During the procedure the disposable can be removed from the instrument channel of the endoscope and a therapy tool may be inserted instead.

The NaviAid™ BGC disposable is intended for single use, while the ASU and SB ASU are re-usable.

Intended Use / Indication for Use:

The NaviAid™ BGC device is an accessory to an endoscope and is intended to ensure positioning of a standard endoscope during endoscopy of the small and large intestine (standard endoscope-i.e., an endoscope that has an instrument channel that is at least 3.7mm diameter and is used for standard endoscopic visualization).

Comparison of Technological Characteristics with the predicate device:

Modification to the NaviAid™ BGC device includes only the addition of the SB ASU as an alternative component to the ASU.

The SB ASU component of the modified NaviAid™ BGC device is identical to the SB ASU component of the cleared NaviAid™ ICVI Device (K110291) and their technological characteristic are the identical. The BGC Disposable was not changed or altered and therefore the modified NaviAid™ BGC disposable is also identical to the cleared NaviAid™ BGC disposable (K102616).

Non-Clinical Performance Data

Performance tests relating to the BGC Disposable component are located in the submission of the first predicate device, the NaviAid™ BGC device (document number K102616).

Performance tests relating to the SB ASU component are located in the submission of the second predicate device, the NaviAid™ ICVI device (document number K110291).

Clinical Performance Data

Not Applicable

Conclusions Drawn from Non-Clinical and Clinical Tests:

The non-clinical tests demonstrated that the modified NaviAid™ BGC device with the alternative SB ASU component meets its design and performance specifications. The modified NaviAid™ BGC device may be safely and effectively used in procedures in order to ensure the positioning of a standard endoscope in endoscopy of the small and large intestine and reach depths of the intestine that may not otherwise be accessible with a standard endoscope device.

Substantial Equivalence:

In summary, the modified NaviAid™ BGC device is substantially equivalent to the cleared NaviAid™ BGC device. The only difference is the addition of the SB ASU as an alternative to the ASU. The intended use, basic technology, principle of operation, specifications and safety requirements of the modified NaviAid™ BGC device and the cleared NaviAid™ BGC are the similar.

The modified NaviAid™ BGC is also substantially equivalent to the cleared NaviAid™ ICVI device. The SB ASU component of the modified NaviAid™ BGC device is identical to the SB ASU component of the cleared NaviAid™ ICVI device. The intended use, basic technology, principle of operation, specifications and safety requirements of the SB ASU are identical.

Consequently, the modified NaviAid™ BGC device is substantially equivalent to the cleared NaviAid™ BGC device and to the cleared NaviAid™ ICVI device. The minor differences do not raise any new questions of safety and effectiveness.

Performance Standards:

1. Electrical & Mechanical Safety Testing (IEC 60601-1)
2. Electromagnetic Compatibility Testing (IEC 60601-1-2)
3. Software Validation (IEC 60601-1-4 & FDA Guidelines)

Results of the above mentioned performance testing (including Electrical & Mechanical Safety, Electromagnetic Compatibility and software validation) are

provided in 510(k) number K110291 of the cleared NaviAid™ ICVI device. Nevertheless, for convenience, the completed Standards Data Form (FDA Form #3654) for these standards is provided in Appendix 11-5 of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mrs. Adva Yoselzon
QA Manager and Director of Clinical & Regulatory Affairs
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ISRAEL

AUG - 9 2011

Re: K111760
Trade/Device Name: NaviAid™ BGC Device
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated: July 28, 2011
Received: August 2, 2011

Dear Mrs. Yoselzon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111760

SECTION 6 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111760

Device Name: NaviAid™ BGC Device

Indications for use:

The NaviAid™ BGC device is an accessory to an endoscope and is intended to ensure positioning of a standard endoscope during endoscopy of the small and large intestine (standard endoscope-i.e., an endoscope that has an instrument channel that is at least 3.7mm diameter and is used for standard endoscopic visualization).

Prescription Use ___√___ OR Over-The-Counter Use___

(Per 21 C.F.R. 801 Subpart D) (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111760